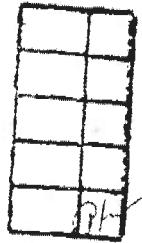


# Tab A-2



## STATE SETTLEMENT AGREEMENT AND RELEASE

### I. PARTIES

This Settlement Agreement ("Agreement") is entered into by the state of Montana and Bayer Corporation ("Bayer"), an Indiana corporation with a principal place of business in Pittsburgh, Pennsylvania, hereinafter referred to as "the Parties."

### II. PREAMBLE

As a preamble to this State Agreement, the Parties agree as follows:

A. This Agreement addresses the claims against Bayer for the conduct described in filings in United States v. Bayer Corporation, Criminal Action No. [to be assigned](District of Massachusetts)(the "Criminal Action"), and in filings in United States ex rel. Couto v. Bayer Corporation, Civil Action No. 00-CV-10339 (District of Massachusetts)(the "Civil Action") for the conduct alleged in Preamble Paragraph F below.

B. On or before April 16, 2003, or some other date as may be determined by the Court, Bayer has agreed to or has entered a plea of guilty pursuant to Fed. R. Crim. P. 11(c)(1)(C) to a one-count Information alleging a violation of Title 21, United States Code, Sections 331(p), 333(a)(2) and 360(j) by failing to list a drug product with the FDA between August and December 1995, namely, Cipro, that was private labeled by Bayer for Kaiser Permanente Medical Care Program ("Kaiser").

C. At all relevant times, Bayer marketed and sold pharmaceutical products nationwide, including among other drugs, two prescription drug products: (1) ciprofloxacin hydrochloride tablets, an antibiotic, marketed under the brand name Cipro®; and (2) nifedipine extended release tablets, an anti-hypertensive, marketed under the brand name Adalat CC® (collectively, "the drugs"). Bayer sold the drugs to various customers including, among others, health maintenance organizations ("HMOs"), hospitals, long term care providers, and chain pharmacies. Two HMOs that purchased the drugs from Bayer were Kaiser and PacifiCare

Health Systems ("PacificCare"). PacificCare purchased the drugs from Bayer through Prescription Solutions, a pharmacy benefit manager and wholly owned subsidiary of PacificCare.

D. Effective August 1995, Bayer agreed to private label Cipro for Kaiser and to sell the private labeled Cipro to Kaiser at a discounted price. The term "private labeled" as used herein means drug product that Bayer sold to a purchaser to which Bayer affixed a label that substituted the purchaser's national drug code ("NDC") for Bayer's NDC number. Effective April 1997, Bayer agreed to private label Adalat CC for Kaiser and to sell the private labeled Adalat CC to Kaiser at a discounted price. Effective October 1998, Bayer agreed to private label Adalat CC for PacificCare and to sell the private labeled Adalat CC to PacificCare at a discounted price.

E. At all material times, Bayer participated in the Medicaid Rebate Program, 42 U.S.C. § 1396r-8, which is part of the federal Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v. As a participant in the Medicaid Rebate Program, Bayer entered into a rebate agreement with the Secretary of the Department of Health and Human Services, which agreement is administered by the Health Care Financing Administration ("HCFA"), currently known as the Center for Medicare and Medicaid Services ("CMS"), and Bayer's drug products were covered by state Medicaid plans that provided medical assistance for outpatient prescription drugs. 42 U.S.C. §§ 1396a(10)(A); 1396d(a)(12), and 1396r-8(a)(1). Under the Medicaid Rebate Program and rebate agreement with HCFA, Bayer generally agreed: (i) to report quarterly to HCFA its average manufacturer price and Best Price for its drug products, as defined by 42 U.S.C. §§ 1396r-8(k)(1) and 1396r-8(c)(1)(C); and (ii) to pay quarterly rebates to the states based on the product of (a) the units of each dosage form and strength paid for under the State Medicaid plan during the rebate period as reported by the state, and (b) the greater of the difference between the average manufacturer price and Best Price, or a minimum rebate percentage of the average manufacturer price, as further defined in 42 U.S.C. § 1396r-8(c)(1).

F. The state of Montana contends that it has certain civil claims against Bayer Corporation under the Medicaid Rebate Program, 42 U.S.C. § 1396r-8, the Drug Pricing Program, 42 U.S.C. § 256b, other federal and state statutes, and/or common law doctrines for engaging in the following conduct:

- (i) The state of Montana contends that, from Third Quarter 1995 through Third Quarter 2000, Bayer knowingly misreported its Best Price to HCFA and underpaid its Medicaid rebates for Cipro tablets by omitting the price of Cipro that was private labeled for Kaiser from its determination of Best Price;
- (ii) The state of Montana contends that, from Second Quarter 1997 through Third Quarter 2000, Bayer knowingly misreported its Best Price to HCFA and underpaid its Medicaid rebates for Adalat CC by omitting the price of Adalat CC that was private labeled for Kaiser and PacifiCare from its determination of Best Price;
- (iii) The state of Montana contends that, in May and June 1999, Bayer knowingly submitted false statements or records to the Office of Inspector General, Office of Audit Services, Department of Health and Human Services ("OIG-OAS") by (a) omitting material information about the price of Cipro tablets that was private labeled for Kaiser; (b) falsely stating that a higher priced package of Cipro was private labeled for Kaiser when it was not; and (c) falsely stating that the actual price at which Bayer sold Cipro to Kaiser was higher than Bayer's reported Best Price;
- (iv) The state of Montana contends that, in First Quarter 1998, Bayer knowingly misreported its Best Price to HCFA and underpaid its Medicaid rebates for Adalat CC by omitting a \$100,000 payment made by Bayer to Prescription Solutions in connection with Adalat CC;
- (v) The state of Montana contends that Bayer knowingly failed to list the Cipro that Bayer private labeled for Kaiser with the FDA to conceal the private labeling arrangement from the FDA and customers of Bayer's Cipro.

Bayer's conduct as described in the Criminal Action, the currently pending claims in the Civil Action, and this Preamble Paragraph are hereafter referred to as the "Covered Conduct."

G. The state of Montana represents that it does not have an administrative claim for exclusion against Bayer under the provisions for mandatory exclusion from the Medicare, Medicaid and other federal health care programs, 42 U.S.C. § 1320a-7(a) or corresponding state statutes, for Bayer's conviction in the Criminal Action or for the Covered Conduct, but alleges that it does have certain administrative claims for exclusion against Bayer under the provisions for permissive exclusion from the Medicare, Medicaid and other federal health care programs, 42 U.S.C. § 1320a-7(b) and corresponding state statutes, for the Covered Conduct.

H. Other than such admissions as Bayer makes in connection with its plea to the Information to which Bayer has agreed to enter a plea of guilty, which Bayer admits, Bayer denies the remaining allegations of the United States, relator(s) and the state of Montana as set forth herein. This Agreement does not constitute an admission by Bayer or evidence of any liability or wrongful conduct.

I. To avoid the delay, expense, inconvenience, and uncertainty of protracted litigation of these claims, the Parties mutually desire to reach a full and final settlement as set forth below.

### III. TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants, and obligations in this Agreement, and for good and valuable consideration, receipt of which is hereby acknowledged, the Parties agree as follows:

1. Bayer agrees to pay to the United States and to the Escrow Agent described below for distribution to the states and the District of Columbia that execute a state settlement agreement that has also been executed by Bayer ("Participating States") the sum of two-hundred, forty-two million, one-hundred twenty-six thousand, five-hundred eighty dollars (\$242,126,580)

(the "Medicaid Settlement Amount") and any pre-transfer interest as set forth in Section III.1.A and III.1.B herein. Payments to the United States and to the Participating States shall be made pursuant to the following terms and conditions:

A. Bayer has agreed to pay to the United States the sum of one-hundred, thirty-three million, one-hundred and sixty-nine thousand, six-hundred and nineteen dollars (\$133,169,619) (the "Federal Medicaid Settlement Amount"), which represents the federal share of the Medicaid Settlement Amount and the share of the Medicaid Settlement Amount payable to the relator(s) in certain federal False Claims Act lawsuit(s). The Federal Medicaid Settlement Amount, plus any pre-transfer interest pursuant to Section III.1.A of the Federal Agreement, shall be paid pursuant to a civil settlement agreement entered between Bayer and the United States (the "Federal Agreement").

B. Bayer agrees to deposit into an escrow account the sum of one-hundred and eight million, nine-hundred, fifty-six thousand, nine-hundred and sixty-one dollars (\$108,956,961) (the "State Medicaid Settlement Amount"), which represents the state-funded portions of the claims settled for the Medicaid programs of all states (except Arizona) and the District of Columbia. Bayer shall pay the State Medicaid Settlement Amount, plus any pre-transfer interest pursuant to Section III.1.B of the Federal Agreement, into the escrow account no later than seven business days after Bayer receives written transfer instructions from the negotiating team for the National Association of Medicaid Fraud Control Units ("NAMFCU Negotiating Team") and following the latest of the dates on which the following occurs. (1) the Federal Agreement is fully executed by the Parties and delivered to Bayer's attorneys, (2) the Escrow Agreement is executed by or on behalf of the Participating States and Bayer, and (3) the Court accepts the Fed. R. Crim. P. 11(e)(1)(C) guilty plea in connection with the Criminal Action as described in Preamble Paragraph II.B, and imposes the agreed upon sentence. The escrow account into which Bayer shall deposit the State Medicaid Settlement Amount shall be an account under the custody and control of the Medicaid Fraud Control Unit of the state of New

York, which shall be designated by the NAMFCU Negotiating Team and which shall act as Escrow Agent and shall retain such funds until their release in accordance with the Escrow Agreement entered into between Bayer and the Medicaid Fraud Control Unit of the state of New York.

C. The total portion of the Medicaid Settlement Amount paid by Bayer in settlement for alleged injury to the Medicaid Program for the state of Montana is \$569,059.57, consisting of a portion paid to the state of Montana under this Agreement and another portion paid to the federal government as part of the Federal Settlement. The individual portion of the State Medicaid Settlement Amount allocable to the state of Montana is the sum of \$190,088.67 ("Individual State Medicaid Settlement Amount").

D. The state of Montana shall be entitled to disbursement of its Individual State Medicaid Settlement Amount from the escrow account pursuant to the terms of the Escrow Agreement, which is attached hereto as Exhibit A and is incorporated by reference herein.

2. In consideration of this Agreement and payment set forth herein and subject to the exceptions from release set forth in Paragraph 3 below, the state of Montana on behalf of itself, its officers, agents, agencies and departments shall release and forever discharge Bayer, its current and former parents, affiliates, divisions, and subsidiaries, and their predecessors, successors and assigns, from any civil or administrative claims for damages or penalties that the state of Montana has or may have relating to the Covered Conduct. The payment of the Medicaid Settlement Amount fully discharges Bayer from any obligation to pay Medicaid-related restitution, damages, and/or any fine or penalty for the Covered Conduct.

3. Notwithstanding any term of this Agreement, the state of Montana specifically does not herein release Bayer, its current and former parents, affiliates, divisions, and subsidiaries, and their predecessors, successors and assigns, and its current and former directors, officers, agents and employees from any and all of the following: (a) any potential criminal, civil or administrative claims arising under state of Montana revenue codes; (b) any criminal

liability not specifically released by this Agreement; (c) any civil or administrative liability that Bayer has or may have under any state statute, regulation, or rule not covered by the release; (d) any liability to the state of Montana (or its agencies) for any conduct other than the Covered Conduct; (e) any claims based upon such obligations as are created by this State Settlement Agreement.

4. In consideration of the obligations of Bayer set forth in this Agreement and payment set forth herein and except as reserved in Paragraph 3 above, the state of Montana agrees to release and refrain from instituting, directing, recommending or maintaining (a) any administrative claim, or (b) any action seeking exclusion from the state of Montana's Medicaid program; against Bayer, its current and former parents, affiliates, divisions, and subsidiaries, and their predecessors, successors and assigns, for the Covered Conduct or for Bayer's conviction in the Criminal Action. Nothing in this Agreement precludes the state of Montana from taking action against Bayer in the event that Bayer is excluded by the federal government, or for conduct and practices other than the Covered Conduct or the conviction in the Criminal Action. The Medicaid Fraud Control Unit for the state of Montana further agrees to refrain from recommending, causing or attempting to cause any administrative action or sanction, including debarment, by any other government agency of the state of Montana for the Covered Conduct or for the conviction in the Criminal Action. The state of Montana does not have the authority to release Bayer from any claims or actions which may be asserted by private payors or insurers, including those that are paid by a State's Medicaid program on a capitated basis, which are not a party to the Medicaid Rebate Program.

5. The making of this Agreement shall not be construed by the state of Montana as a basis for the exclusion of any of Bayer's products from the state of Montana's formulary or as a basis for a change in status regarding prior authorization.

6. The state of Montana agrees to dismiss with prejudice any lawsuit specifically as to Bayer, including any state qui tam "whistleblower" lawsuit, in which the state has intervened

and/or has the authority to dismiss, currently pending against Bayer in the courts of the state of Montana, relating to the Covered Conduct.

7. This Agreement is expressly conditioned upon acceptance of Bayer's plea of guilty in the Criminal Action. In consideration of the acceptance of Bayer's plea of guilty in the Criminal Action, the state of Montana agrees that it shall not investigate, prosecute, or refer for prosecution or investigation to any agency, Bayer, its current and former parents, affiliates, divisions, and subsidiaries, and their predecessors, successors and assigns, for the Covered Conduct.

8. Bayer fully and finally releases the state of Montana, its agencies, employees, servants, and agents from any claims (including attorneys fees, costs, and expenses of every kind and however denominated) which Bayer has asserted, could have asserted, or may assert in the future against the state of Montana, its agencies, employees, servants, and agents, related to or arising from the investigation and prosecution of the Covered Conduct up to the effective date of this Settlement Agreement.

9. Nothing in this agreement shall preclude either Bayer or the state of Montana from pursuing any rights they have pursuant to the Medicaid Rebate Program as to adjustments to Rebate Payments, except to the extent that no adjustment shall be made to Best Price based upon Covered Conduct, which this agreement settles.

10. Bayer waives and will not assert any defenses it may have to any criminal prosecution or administrative action relating to the Covered Conduct which defenses may be based in whole or in part on a contention that, under the Double Jeopardy Clause of the Fifth Amendment of the Constitution or Excessive Fines Clause of the Eighth Amendment of the Constitution, this Settlement Agreement bars a remedy sought in such criminal prosecution or administrative action. Provided, however, that nothing in this paragraph is intended to, or will operate to, limit the scope of Paragraph 7, in which the state of Montana agrees not to prosecute or investigate Bayer for certain conduct.

11. Except as otherwise specified herein, this Agreement is intended to be for the benefit of the Parties only, and by this instrument the Parties do not release any claims against any other person or entity, including but not limited to any individual or entity that purchased Cipro and Adalat from Bayer.

12. Nothing in any provision of this Agreement constitutes an agreement by the state of Montana concerning the characterization of the Medicaid Settlement Amount for purposes of the state internal revenue laws.

13. In addition to all other payment and responsibilities under this Agreement, Bayer agrees to pay all reasonable travel costs and expenses of the NAMFCU Negotiating Team. Bayer will pay this amount by separate check or wire transfer made payable to the National Association of Medicaid Fraud Control Units after the Participating States execute this Agreement.

14. Bayer covenants to cooperate fully and truthfully with the state of Montana in any ongoing investigation or investigation commenced within five years of the effective date of this Agreement of individuals and entities not specifically released by this Agreement (including any parties with whom Bayer has or has had a business or professional relationship, including but not limited to vendors, contractors, partners, joint venturers, physicians, and referral sources) relating to the Covered Conduct.

15. Notwithstanding any provision of this Agreement, Bayer is not required to (1) request of its present or former officers, directors, employees or agents that they forego seeking the advice of an attorney nor that they act contrary to that advice; (2) take any action against its directors, employees or agents for following their attorney's advice or for failing to submit to an interview or otherwise cooperate with the state of Montana; or (3) waive any privilege or claim of work product. The failure of any individual to submit to an interview or otherwise to refuse to cooperate with the state of Montana shall not constitute a breach of this Agreement by Bayer.

16. Bayer shall enter into an Addendum to its existing Corporate Integrity Agreement with HHS-OIG in connection with this matter.

17. Bayer represents that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

18. The undersigned Bayer signatory represents and warrants authorization by the Board of Directors to execute this Agreement. The undersigned state of Montana signatories represent that they are signing this Agreement in their official capacities and they are authorized to execute this Agreement on behalf of the state of Montana through their respective agencies and departments.

19. This Agreement is governed by the laws of the state of Montana.

20. This Agreement is effective on the date of signature of the last signatory to the Agreement.

21. This Agreement shall be binding on all successors, transferees, heirs and assigns of the Parties, provided, however, this Agreement shall not apply to the products of an acquiring company or a company merging with Bayer except to the extent such company, as a result of the acquisition of or merger with Bayer, becomes involved in the sales, marketing or pricing of, or Medicaid Drug Rebate program obligations associated with, drug and biologic products for which the Federal health care programs provide reimbursement ("Government Reimbursed Products") originally manufactured by Bayer prior to the merger or acquisition, in which case the obligations of this agreement shall apply only to those products which had been Government Reimbursed Products when they were manufactured by Bayer.

22. This Agreement constitutes the complete agreement between the Parties with regard to the Covered Conduct. This Agreement may not be amended except by written consent of the Parties.

23 Each party agrees to perform any further acts and to execute and deliver any further documents reasonably necessary to carry out this Agreement. This Agreement may be executed in counterparts, each of which shall constitute an original and all of which shall constitute one and the same Agreement.

For the state of Montana:

By: Gordon Hage Dated: 4-17-03

Title: Director - MT MFCU

For the state of Montana Medicaid Program:

By: John T. Clappier Dated: 5/15/03

Title: Deputy Director - DPHHS

BAYER CORPORATION

By: Jon R. Wyne Dated: 12/31/03  
JON R. WYNE  
Senior Vice President and Treasurer  
Bayer Corporation



By: Paul E. Kalb Dated: 12/23/03  
PAUL E. KALB  
JAMES C. STANSEL  
Sidley Austin Brown & Wood, LLP  
1501 K Street, NW  
Washington, DC 20005  
Counsel to Bayer Corporation

WRITTEN INSTRUCTIONS FOR THE TRANSFER OF SETTLEMENT FUNDS

ESCROW AGREEMENT

For good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Medicaid Fraud Control Unit of the State of New York and the Bayer Corporation ("Bayer") hereby agree as follows:

1. The Escrow Agent agrees to hold the State Settlement Amount of \$108,956,961 plus pre-transfer interest (in the amount of \$10,448 per day beginning on March 25, 2003 and continuing until and including the day before transfer is completed into the Escrow Account) paid to the States by Bayer pursuant to the Federal Settlement Agreement and the Model State Settlement Agreement in an account maintained by the Medicaid Fraud Control Unit of the State of New York and acting as the Escrow Agent.

2. The Escrow Agent agrees to dispose of the monies held in the Escrow Account pursuant to directions to be provided by the NAMFCU Negotiating Team upon the receipt of fully executed settlement agreements between Bayer and the participating states and the District of Columbia (except Arizona). Any state or the District of Columbia that has executed a settlement agreement that has also been executed by Bayer shall be a "Participating State."

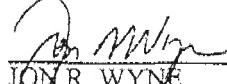
3. The parties shall make best efforts to complete the settlement in a timely manner.

4. Any monies attributable to a state or the District of Columbia which, by the date of distribution, determines not to participate ("Non-Participating State(s)") shall be disbursed to Bayer with the appropriate interest (both pre-transfer and pending distribution for said Non-Participating State that has accrued to the date of distribution, if any). Said distribution of a Non-Participating State share back to Bayer shall occur within 30 days of the distribution to Participating States or by further agreement of the parties.

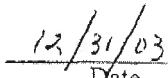
The undersigned Bayer signatory represents and warrants that he is authorized to execute this Agreement. The undersigned representative of the Medicaid Fraud Control Unit of the State of New York represents and warrants that he is signing this Agreement in his official capacity.

  
\_\_\_\_\_  
PATRICK LUPINETTI  
Director, Special Projects  
Medicaid Fraud Control Unit of the State of New York

  
\_\_\_\_\_  
Date

  
\_\_\_\_\_  
JON R. WYNE  
Senior Vice President and Treasurer  
Bayer Corporation



  
\_\_\_\_\_  
Date

STATE OF MONTANA  
DISPOSITION OF PROCEEDS FROM  
BAYER CORPORATION  
TOTAL MEDICAID SETTLEMENT (STATE/FEDERAL) IS \$ 569,059.57

1	State Share of Medicaid Restitution	\$ <u>102,957.99</u>
2	State Share of Medicaid Penalties	\$ <u>87,130.68</u>
3	Total Medicaid State Settlement	\$ <u>190,088.67</u> *

\*THESE ARE STATE MONIES ONLY; DO NOT SEND OR CREDIT ANY AMOUNT TO THE FEDERAL GOVERNMENT.

IF ANY MFCU STATES HAVE QUESTIONS ON HOW TO REPORT THESE MONIES AND/OR PROPERLY USE THE PENALTY PLEASE DIRECT QUESTIONS TO:

JOHN BETTAC, DIRECTOR  
MEDICAID OVERSIGHT STAFF  
OFFICE OF THE INSPECTOR GENERAL  
(202) 619-3557

DISTRIBUTION